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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/325,095
Filing Date: June 03, 1999
Appellant(s): HILES ET AL.

Norman Hanson, Esq.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 17, 2005 appealing from the Office action mailed January 27, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

The brief is deficient because appellant failed to refer to the subject matter of the independent claim by page and line number. Appellant has pointed to pages 1, lines 34- page 2, line 2 and page 3, lines 29-35. Pages 1-3 are not drawn to a method of determining expression of a gene which encodes a human polypeptide that has PI3

kinase activity and a molecular weight of about 110 kiladaltons as determined by SDS-PAGE. Rather pages 1-2 are drawn to the association of PI kinase activity being of particular interest since increased turnover and phosphorylated derivatives have been implicated in the action of hormones, growth factors and the transformation of cells. Page 3, is drawn to PI3-kinase being a potential signaling protein and that these proteins contain one or more *src* homology domains (SH2). There is no concise explanation of a method for determining expression of a gene and the correlation that determining hybridization determines expression of said gene as instantly claimed in claim 51. Furthermore, there is no reference to the specification by page and line number, of the instantly claimed invention. Therefore the summary of claimed subject matter contained in the brief is deficient.

(6) Grounds of Rejection to be Reviewed on Appeal

Withdrawn Rejections

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

The written description rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, first paragraph;

The rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, second paragraph for omitting essential steps; and

The indefiniteness rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, second paragraph.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-58 and 60-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kiladaltons (kD) comprising: contacting a sample with a nucleic acid

molecule which hybridizes specifically to a transcript of said gene, wherein said transcript is RNA or coda, and selected from the group consisting of: a) the nucleotide sequence set forth in SEQ ID NO: 32; b) the nucleotide sequence set forth in SEQ ID NO:35; and c) the nucleotide sequence which hybridizes to the complement of at least one of a) and b), at 1MNaCl, 10xDenhardt's solutions; 50mM Tris-HCl (pH 7.4); 10mM EDTA; 0.1% SDS; 100ug/ml denatured herring sperm DNA at 65°C for 16 hours, followed by a wash of 2XSSC; 0.1% SDS at 42°C, or a wash of 0.5XSSC/0.1% SDS at 50°C, or a wash at 0.1XSSC/0.1% SDS at 65°C, or a wash at 0.1XSSC/0.1% SDS at 68°C and determining said hybridization as a determination of expression of said gene.

There is no teaching within the specification for appellants' invention being drawn to a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising: contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA, and selected from the group consisting of: a) the nucleotide sequence set forth in SEQ ID NO: 32; b) the nucleotide sequence set forth in SEQ ID NO:35; and c) the nucleotide sequence which hybridizes to the complement of at least one of a) and b), at the recited conditions and determining hybridization as a determination of expression of said gene.

There is no disclosure whatsoever that the nucleotide sequence of the invention could be used in a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD. There is no disclosure that the nucleotide sequences set forth in SEQ ID

NO: 32 and SEQ ID NO:35 can be contacted with a sample comprising a nucleic acid molecule and said molecule specifically hybridizes to the sequences wherein said hybridization determines the expression of said gene. There is no disclosure that an undisclosed nucleotide sequence will hybridizes to the complement of SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions and wherein said hybridization determines the expression of said gene. Moreover, there is no teaching in the specification that discloses the identity of the undisclosed nucleotide sequence as described in section c) which will hybridizes to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions to thereby determine gene expression. Finally, there is no passage in the specification drawn to hybridizing the human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD that is correlated to a method for the determination of gene expression, which in-turn encodes a human polypeptide that has PI3 kinase activity, and has a molecular weight of about 110kD as determined by SDS-PAGE.

The specification teaches hybridization and Polymerase Chain Reaction (PCR) techniques at pages 39 and 41 of the instant specification, however there is no contemplation that such methods should be applied for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising the recited steps. Neither is the use of hybridization and PCR for the determination of gene expression implied in the teachings of the specification. The specification contemplates the use of these techniques in a completely different context, such as for gene cloning. The hybridization process

disclosed by the specification is a process whereby two complementary nucleic acid strands form a double helix during an annealing period thus allowing for the detection of specific nucleotide sequences. Therefore the detection of specific nucleotide sequences is not used with a method for determining gene expression. Moreover, the hybridization techniques fail to provide adequate support for an unrelated method drawn to determining gene expression. PCR allows for the DNA to be amplified a billion-fold thereby making numerous copies of the DNA. There is no contemplation that this amplification process is related to or used with a method for determining gene expression. Appellants' have constantly failed to point to by page and line number support of the instantly claimed method.

As to the dependent claims, SEQ ID NO: 15-19, 21-22, 24-25, 27 and 29 are disclosed as being primers, see pages 39-41. These sequences are not disclosed as nucleic acid molecules which specifically hybridize to a transcript of the claimed gene for use in method of determination, thus there is no support for these claims. Pages 38-39, 41-42 and 52-53 of the instant specification recites that SEQ ID NO: 15-19, 21-22, 24-25, 27 and 29 are useable as primers and not as radiolabelled oligonucleotides, detection reagents, or sequences useable in a method for determining gene expression. Moreover, it is noted that SEQ ID NO: 12 and 14 are disclosed by the specification as being detection reagents, see page 38 in experiments for cloning polypeptide p110 and not as oligonucleotide primers, as recited by claim 57. Therefore, there is no support for the recited claim limitations.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. Thus, the instant claims are rejected for being drawn to new matter.

(10) Response to Argument

Response to Arguments Traversing the Rejection of Claims 51-58 and 60-61 Under 35 U.S.C. 112, first paragraph

In response to appellants' assertion that the claims do not incorporate new matter, it is noted that appellants' have failed to point to support in the specification for a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising a contact step wherein a nucleic acid molecule hybridizes specifically to a transcript of said gene and the determination of said hybridization determines the expression of said gene. It is further noted that even appellants' summary of invention section has failed to point to support within the specification for the claimed method. Moreover, there is no support for a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA, and selected from the group consisting of a) the nucleotide

sequence set forth in SEQ ID NO: 32; b) the nucleotide sequence set forth in SEQ ID NO:35; and c) the nucleotide sequence which hybridizes to the complement of at least one of a) and b), at 1MNaCl, 10xDenhardt's solutions; 50mM Tris-HCl (pH 7.4); 10mM EDTA; 0.1% SDS; 100ug/ml denatured herring sperm DNA at 65°C for 16 hours, followed by a wash of 2XSSC; 0.1% SDS at 42°C, or a wash of 0.5XSSC/0.1% SDS at 50°C, or a wash at 0.XSSC/0.1% SDS at 65°C, or a wash at 0.1XSSC/0.1% SDS at 68°C and determining said hybridization as a determination of expression of said gene within appellants' entire brief.

Appellants' assert that the examiner seems to confuse gene expression and protein expression. However, the issue of gene expression versus protein expression is irrelevant with respect to the issue of whether the claimed invention finds support in the application as filed. Appellants' are reminded that the issue is that the claimed subject matter is not disclosed in the original application therefore such claims have been rejected on the grounds that they recite method steps without support in the original disclosure under 35 U.S.C. 112, first paragraph. Such claims are rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, see *Waldemar Link, GmbH & Co. v. Osteonics Corp*. 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP §2163.06 - §2163.07(b) for a discussion of the

relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only includes the addition of wholly unsupported subject matter, but may also include the omission of a step from a method.

In this case, the new matter issue is drawn to the method for determining gene expression that was not disclosed in the original specification, claims, or drawings thus the claims are rejected accordingly. Appellants' assert that based on well known principles of molecular biology and that there is adequate support in the specification for determining gene expression from hybridization. However, there is no disclosure in the specification as filed that appellants' contemplate that their invention includes a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD. Appellants' have failed to point to support within the instant specification for a method of using the nucleotide sequences set forth in SEQ ID NO:32 and SEQ ID NO:35 can be contacted with a sample comprising a nucleic acid molecule to determine the expression of said gene. Appellants' have failed to point to adequate support disclosing that the undisclosed nucleotide sequence will hybridize to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions and wherein said hybridization determines the expression of said gene. Appellants' have failed to point to by page and line number for a teaching in the specification that discloses the identity of the undisclosed nucleotide sequence as described in section c) which will hybridizes to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions to thereby determine gene expression. Finally, appellants' have failed to state where the

specification provides an outline, protocol, experiment or even a working example for a method of determining hybridization as an act for the determination of gene expression wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110kD as determined by SDS-PAGE. Thus, in view of appellants' failure to point to support for the claimed method in the specification as filed, thus the rejection is proper.

Finally, appellants' assert that very high stringency conditions are recited. However this assertion is irrelevant with respect to the new matter rejection. The issue is not whether gene expression can be detected at the stringency conditions stated but that the specification fails to contain a written description of a method of determination using hybridization techniques for the purpose of determining gene expression. Therefore, in view of appellants' failure to provide support, the rejection is maintained for the reasons stated above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Ja-Na Hines

March 13, 2005

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